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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

January 7, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 19

Gary A. Duclos
President and Chief Executive Officer
American Agco Corporation
545 Hardman Avenue
South St. Paul, Minnesota 55075

Dear Mr. Duclos:

An investigation of your medicated feed mill located at South St. Paul, MN, conducted by our investigators during November 20-21 and 28, 2001, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, Part 225 [21 CFR 225]). Such deviations cause feeds manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found deficiencies in the areas of Product Quality Control and Record Retention, including the lack of maintaining daily inventory records for each drug used, failure to make daily comparisons between the actual amount of drug used and the theoretical amount used, failure to maintain complete receipt records for incoming drugs, failure to maintain a complete master record file, and failure to store drugs to maintain their identify and strength.

The above is not intended as an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction,

and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2).

This letter constitutes official notification under the law. Based on the results of the November 2001, inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

We have received Dr. James E. Sowers' November 28, 2001, response to the form FDA-483 issued on November 28, 2001. The corrective actions that you have taken or plan to take, in combination with our review of your Quality Assurance Policy, appear to be adequate with two notable exceptions. We are concerned that your plans may not fully address the need to maintain sufficient well-trained personnel to prevent the reoccurrence of these CGMP violations. Additionally, we are interested in the findings, particularly if discrepancies were found and corrective actions taken, following your reconciling of ~~~ drug premix inventory and subsequent ~~~ review. We ask that you address these concerns in your written reply to this Warning Letter.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps being taken to correct each noted CGMP violation, including an explanation of your drug reconciliation findings and follow up actions plus the planned activities necessary to assure that similar violations will not recur. Include copies of any available documentation demonstrating that corrections have been made. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed.

Your response should be sent to Acting Compliance Officer Greg A. Abel at the address on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

GAA/ccl